



## **Recommendations for the Use of Antiretroviral Drugs in Pregnant Women with HIV Infection and Interventions to Reduce Perinatal HIV Transmission in the United States**

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# Maternal HIV Testing and Identification of Perinatal HIV Exposure

(Last updated December 24, 2019; last reviewed December 24, 2019)

## Panel's Recommendations

- HIV testing is recommended as standard of care for all sexually active women and should be a routine component of preconception care **(AII)**.
- All pregnant women should be tested as early as possible during each pregnancy (see [Laboratory Testing for the Diagnosis of HIV Infection: Updated Recommendations](#) and [Recommended Laboratory HIV Testing Algorithm for Serum or Plasma Specimens](#) from the Centers for Disease Control and Prevention [CDC]) **(AII)**.
- Partners of pregnant women should be encouraged to undergo HIV testing when their status is unknown **(AIII)**.
- Repeat HIV testing in the third trimester is recommended for pregnant women with negative initial HIV antibody tests who are at increased risk of acquiring HIV, including those who are receiving care in facilities that have an HIV incidence of  $\geq 1$  case per 1,000 pregnant women per year, those who reside in jurisdictions with elevated HIV incidence, or those who reside in states that require third-trimester testing (see [Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings from CDC](#)) **(AII)**.
- Expedited HIV testing should be performed during labor or delivery for any woman with undocumented HIV status; testing should be available 24 hours a day, and results should be available within 1 hour **(AII)**. If results are positive, intrapartum antiretroviral (ARV) prophylaxis should be initiated immediately (AI), and infants should receive an ARV regimen that is appropriate for infants who are at higher risk of perinatal HIV transmission as soon as possible, pending results of supplemental HIV testing **(AII)**. The mother should not breastfeed unless supplemental HIV testing is negative **(AII)**. See [Antiretroviral Management of Newborns with Perinatal HIV Exposure or HIV Infection](#) for guidance.
- Women who were not tested for HIV before or during labor should undergo expedited HIV antibody testing during the immediate postpartum period (or their newborns should undergo expedited HIV antibody testing) **(AII)**. If the results for the mother or infant are positive, an appropriate infant ARV drug regimen should be initiated immediately, and the mother should not breastfeed unless supplemental HIV testing is negative **(AII)**. See [Antiretroviral Management of Newborns with Perinatal HIV Exposure or HIV Infection](#) for guidance.
- Results of maternal HIV testing should be documented in the newborn's medical record and communicated to the newborn's primary care provider **(AIII)**.
- HIV testing is recommended for infants and children in foster care and adoptees for whom maternal HIV status is unknown **(AIII)**.

**Rating of Recommendations:** A = Strong; B = Moderate; C = Optional

**Rating of Evidence:** I = One or more randomized trials in children<sup>†</sup> with clinical outcomes and/or validated endpoints; I\* = One or more randomized trials in adults with clinical outcomes and/or validated laboratory endpoints with accompanying data in children<sup>†</sup> from one or more well-designed, nonrandomized trials or observational cohort studies with long-term clinical outcomes; II = One or more well-designed, nonrandomized trials or observational cohort studies in children<sup>†</sup> with long-term outcomes; II\* = One or more well-designed, nonrandomized trials or observational studies in adults with long-term clinical outcomes with accompanying data in children<sup>†</sup> from one or more similar nonrandomized trials or cohort studies with clinical outcome data; III = Expert opinion

<sup>†</sup> Studies that include children or children/adolescents, but not studies limited to post-pubertal adolescents

## Preconception Counseling and Care for Women of Childbearing Age Living with HIV (Last updated December 24, 2019; last reviewed December 24, 2019)

### Panel's Recommendations

- Discuss reproductive desires with all women of childbearing age on an ongoing basis throughout the course of their care (AIII).
- Provide information about effective and appropriate contraceptive methods to reduce the likelihood of unplanned pregnancy (AI).
- During preconception counseling, provide information on safe sex and encourage the elimination of alcohol, tobacco, and other drugs of abuse; if elimination is not feasible, clinicians should provide appropriate treatment (e.g., methadone or buprenorphine) or counsel patients on how to manage health risks (e.g., use of a syringe services program) (AII).
- Women with HIV should attain maximum viral suppression before attempting conception for their own health, to prevent sexual HIV transmission to partners without HIV (AI), and to minimize the risk of perinatal HIV transmission to the infant (AI).
- When selecting or evaluating an antiretroviral (ARV) regimen for women of childbearing age with HIV, consider a regimen's effectiveness, a woman's hepatitis B status, the teratogenic potential of the drugs in the ARV regimen, and the possible adverse outcomes for the mother and fetus (AII). See [Teratogenicity](#) and [Recommendations for Use of Antiretroviral Drugs During Pregnancy](#) for more information. The Panel on Treatment of Pregnant Women with HIV Infection and Prevention of Perinatal Transmission emphasizes the importance of counseling and informed decision-making regarding all ARV regimens for people with HIV (AIII).
- HIV infection does not preclude the use of any contraceptive method; however, drug-drug interactions between hormonal contraceptives and antiretrovirals should be considered (AII).

**Rating of Recommendations:** A = Strong; B = Moderate; C = Optional

**Rating of Evidence:** I = One or more randomized trials with clinical outcomes and/or validated laboratory endpoints; II = One or more well-designed, nonrandomized trials or observational cohort studies with long-term clinical outcomes; III = Expert opinion

## Reproductive Options for Couples When One or Both Partners are Living with HIV (Last updated December 24, 2019; last reviewed December 24, 2019)

### Panel's Recommendations

#### For Couples Who Want to Conceive When One or Both Partners are Living with HIV:

- Expert consultation is recommended to tailor guidance to couples' specific needs **(AIII)**.
- Both partners should be screened and treated for genital tract infections before attempting to conceive **(AII)**.
- Partners with HIV should achieve sustained viral suppression (e.g., two recorded measurements of plasma viral loads that are below the limits of detection at least 3 months apart) before attempting conception to maximize their health, prevent HIV sexual transmission **(AI)** and, for pregnant persons with HIV, to minimize the risk of HIV transmission to the infant **(AI)**.
- For couples with differing HIV statuses, sexual intercourse without a condom allows for conception with effectively no risk of sexual HIV transmission to the partner without HIV when the partner with HIV is on antiretroviral therapy (ART) and has achieved sustained viral suppression **(BII)**.
- Additional guidance may be required in the following scenarios:
  - The partner with HIV has not achieved sustained viral suppression or the partner's HIV viral suppression status is unknown,
  - There are concerns that the partner with HIV may be inconsistently adherent to ART during the periconception period, or
  - The provider needs to share additional information with the patient regarding options to prevent sexual HIV transmission during the periconception period.
- In these circumstances, providers may choose to counsel their patient about the following options:
  - Administration of antiretroviral pre-exposure prophylaxis (PrEP) to the partner without HIV is recommended to reduce the risk of sexual acquisition of HIV **(AI)**. Timing condomless sex to coincide with ovulation (peak fertility) is an approach that can optimize the probability of conception **(AIII)**.
  - Even within couples with differing HIV statuses who attempt conception when the partner with HIV has achieved viral suppression, some partners without HIV may still choose to take PrEP **(CIII)**.

**Rating of Recommendations:** A = Strong; B = Moderate; C = Optional

**Rating of Evidence:** I = One or more randomized trials with clinical outcomes and/or validated laboratory endpoints; II = One or more well-designed, nonrandomized trials or observational cohort studies with long-term clinical outcomes; III = Expert opinion

## General Principles Regarding Use of Antiretroviral Drugs during Pregnancy

### Panel's Recommendations

- Initial evaluation of pregnant women living with HIV should include an assessment of HIV disease status and plans to initiate, continue, or modify antiretroviral therapy (ART) **(AI)**. The National Perinatal HIV Hotline (1-888-448-8765) provides free clinical consultation on all aspects of perinatal HIV care.
- All pregnant women with HIV should initiate ART as early in pregnancy as possible, regardless of their HIV RNA level or CD4 T lymphocyte count, for their own health and to prevent perinatal HIV transmission and secondary sexual transmission **(AI)**. The Panel on Treatment of Pregnant Women with HIV Infection and Prevention of Perinatal Transmission recommends that individuals with HIV maintain an HIV viral load that is below the limit of detection during pregnancy and postpartum and throughout their lives **(AII)**.
- To minimize the risk of perinatal transmission, antiretroviral (ARV) drugs should be administered at all time points (including antepartum and intrapartum) to the woman as well as postnatally to the neonate **(AI)**.
- The known benefits and potential risks of all medications, including ARV drugs used during pregnancy and postpartum, should be discussed with all women with HIV **(AIII)**.
- The importance of adherence to ARV drug regimens should be emphasized during patient counseling **(AII)**.
- ARV drug-resistance genotype evaluations or assays should be performed before starting ARV drug regimens in women who are ARV-naïve **(AII)** or ARV-experienced **(AIII)** and before modifying ARV drug regimens **(AII)** in women whose HIV RNA levels are above the threshold for resistance testing (i.e., >500 copies/mL to 1,000 copies/mL).
- In pregnant women who are not already receiving ART, ART should be initiated before results of drug-resistance testing are available, because **earlier viral suppression has been associated with lower risk of transmission**. When ART is initiated before results are available, the regimen should be modified, if necessary, based on resistance assay results **(BIII)**.
- Coordination of services among prenatal care providers, primary care and HIV specialty care providers, and, when appropriate, mental health and substance use disorder treatment services, intimate partner violence support services, and public assistance programs is essential to help ensure that women with HIV adhere to their ARV drug regimens **(AII)**.
- Providers should initiate counseling about key intrapartum and postpartum considerations during pregnancy, including mode of delivery, lifelong HIV therapy, family planning and contraceptive options, infant feeding, infant ARV prophylaxis, and timing of infant diagnostic testing **(AIII)**.

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## Teratogenicity (Last updated December 12, 2019; last reviewed December 12, 2019)

### Panel's Recommendations

- All cases of antiretroviral (ARV) drug exposure during pregnancy should be reported to the [Antiretroviral Pregnancy Registry \(AIII\)](#).
- Based on multiple studies indicating no difference in rates of total birth defects for first-trimester exposure compared with later ARV drug exposures, women can be counseled that ARV drugs during pregnancy generally do not increase the risk of birth defects (**BIII**); a possible exception is a small increased risk of neural tube defects (NTDs) with dolutegravir (DTG) use during the periconception period. Providers should be aware that data on the risks of birth defects for many ARV drugs are limited.

#### Updated Panel Recommendations Regarding the Use of Dolutegravir at the Time of Conception and During Pregnancy:

- DTG exposure around the time of conception has been associated with a small but significant increase in the risk of infant NTDs in Botswana (0.3%), where food is not routinely fortified with folate. Although this risk was higher than the risk for NTDs in infants born to women who were receiving efavirenz (0.05%) and women without HIV (0.08%), there are not enough data to determine the risk of NTDs with preconception use of all *Preferred* and *Alternative* regimens, including DTG, in the United States. Based on the available evidence, the Panel on Treatment of Pregnant Women with HIV Infection and Prevention of Perinatal Transmission (the Panel) recommends DTG as a **Preferred drug for pregnant women, irrespective of trimester (AII)**, and an **Alternative drug for women who are trying to conceive (AIII)**.
- The Panel emphasizes the importance of counseling and informed decision-making regarding all ARV regimens for people with HIV (**AIII**). For additional information, see [Appendix D: Dolutegravir Counseling Guide for Health Care Providers](#).
- Clinicians should discuss future reproductive plans and timing as well as the risks and benefits of conceiving on specific ARV medications and use of appropriate contraceptive options to prevent unintended pregnancy (**AIII**).
- Folic acid is known to prevent NTDs in the general population. All pregnant women and women who might conceive should take at least 400 mcg of folic acid daily (**AI**). There is no established link between the use of DTG and impaired folate metabolism, nor is there evidence that folate supplementation prevents DTG-associated NTDs.
- For additional information, see [Updated Guidance about the Use of Dolutegravir in Pregnancy](#) in [Recommendations for Use of Antiretroviral Drugs During Pregnancy, Preconception Counseling and Care for Women of Childbearing Age Living with HIV](#), [Pregnant Women Living with HIV Who Are Currently Receiving Antiretroviral Therapy](#), and [Dolutegravir](#).

**Rating of Recommendations:** A = Strong; B = Moderate; C = Optional

**Rating of Evidence:** I = One or more randomized trials with clinical outcomes and/or validated laboratory endpoints; II = One or more well-designed, nonrandomized trials or observational cohort studies with long-term clinical outcomes; III = Expert opinion

## Combination Antiretroviral Drug Regimens and Maternal and Neonatal Outcomes

(Last updated December 24, 2019; last reviewed December 24, 2019)

### Panel's Recommendations

- Clinicians should be aware of a possible increased risk of adverse neonatal outcomes (e.g., preterm delivery) in pregnant women who are receiving antiretroviral therapy (ART). However, given the clear benefits of ART for both a woman's health and the prevention of perinatal transmission, HIV treatment should not be withheld due to concern for adverse pregnancy outcomes (**AII**).

**Rating of Recommendations:** A = Strong; B = Moderate; C = Optional

**Rating of Evidence:** I = One or more randomized trials with clinical outcomes and/or validated laboratory endpoints; II = One or more well-designed, nonrandomized trials or observational cohort studies with long-term clinical outcomes; III = Expert opinion

## Recommendations for Use of Antiretroviral Drugs during Pregnancy: Overview (Last updated December 12, 2019; last reviewed December 12, 2019)

### Panel's Recommendations

- When choosing an antiretroviral (ARV) drug regimen for a pregnant woman, providers and patients should consider multiple factors, including adverse effects, drug interactions, pharmacokinetics (PKs), convenience of the individual drugs and drug combinations in the regimen, available pregnancy safety and outcome data, and the patient's resistance test results and comorbidities (AIII).
- The same regimens that are recommended for the treatment of nonpregnant adults should be used in pregnant women when sufficient data suggest that appropriate drug exposure is achieved during pregnancy; clinicians should weigh the risks of adverse effects for women, fetuses, or infants against the benefits of these regimens and recognize that there are often incomplete data on the safety of ARV drugs in pregnancy (AII). For more information, see Tables 4 and 5.
- In most cases, women who present for obstetric care on fully suppressive ARV regimens should continue their current regimens (AIII).
- PK changes in pregnancy may lead to lower plasma levels of drugs and necessitate increased doses, more frequent dosing, boosting, or more frequent viral load monitoring (AII).

### Updated Panel Recommendations Regarding the Use of Dolutegravir in Pregnancy:

- Dolutegravir (DTG) exposure around the time of conception has been associated with a small but significant increase in the risk of infant neural tube defects (NTDs) in Botswana (0.3%). This risk was higher than the risk for NTDs in infants born to women who were receiving efavirenz (0.05%) and women without HIV (0.08%). There are not enough data to determine the risk of NTDs with preconception use of all Preferred and Alternative regimens, including DTG, in the United States. Based on the available evidence, the Panel on Treatment of Pregnant Women with HIV Infection and Prevention of Perinatal Transmission (the Panel) recommends DTG as a Preferred drug for pregnant women, irrespective of trimester (AII), and an Alternative drug for women who are trying to conceive (AIII).
- The Panel emphasizes the importance of counseling and informed decision-making regarding all ARV regimens for people with HIV (AIII). For additional information, see Preconception Counseling and Care for Women of Childbearing Age Living with HIV, Teratogenicity, Appendix D: Dolutegravir Counseling Guide for Health Care Providers, and Tables 4 and 5.
- When DTG use is continued after delivery, clinicians should discuss reproductive desires, the risks and benefits of conceiving on DTG, and contraceptive options (AIII). See Preconception Counseling and Care and Postpartum Care for more information.
- Folic acid is known to prevent NTDs in the general population. All pregnant women and women who might conceive should take at least 400 mcg of folic acid daily (AI). There is no established link between the use of DTG and impaired folate metabolism, nor is there evidence that folate supplementation prevents DTG-associated NTDs.

**Rating of Recommendations:** A = Strong; B = Moderate; C = Optional

**Rating of Evidence:** I = One or more randomized trials with clinical outcomes and/or validated laboratory endpoints; II = One or more well-designed, nonrandomized trials or observational cohort studies with long-term clinical outcomes; III = Expert opinion

## Pregnant Women Living with HIV Who Have Never Received Antiretroviral Drugs (Antiretroviral Naive) (Last updated December 12, 2019; last reviewed December 12, 2019)

### Panel's Recommendations

- Antiretroviral therapy (ART) is recommended for all pregnant women living with HIV to reduce the risk of perinatal transmission of HIV and to optimize the health of the mother **(AI)**. Initiating ART as soon as possible in pregnant women who have never received antiretroviral (ARV) drugs is recommended, based on data demonstrating that earlier virologic suppression is associated with a lower risk of transmission **(AII)**.
- The results of HIV drug-resistance studies should guide the selection of antiretroviral (ARV) regimens in women whose HIV RNA levels are above the threshold for resistance testing (i.e., >500 copies/mL to 1,000 copies/mL), unless drug-resistance studies have already been performed (see [Antiretroviral Drug Resistance and Resistance Testing in Pregnancy](#)) **(AII)**. When ART is initiated before the results of the drug-resistance assays are available, the ARV regimen should be modified, if necessary, based on the resistance assay results **(BIII)**.
- ARV regimens that are *Preferred* for the treatment of pregnant women with HIV who are ARV-naïve include: a dual-nucleoside reverse transcriptase inhibitor combination (abacavir plus lamivudine or tenofovir disoproxil fumarate plus either emtricitabine or lamivudine) and either a ritonavir-boosted protease inhibitor (atazanavir/ritonavir or darunavir/ritonavir) or an integrase strand transfer inhibitor (dolutegravir **[irrespective of trimester]** or raltegravir; see [Table 4](#) and [Updated Guidance about the Use of Dolutegravir in Pregnancy](#) in [Recommendations for the Use of Antiretroviral Drugs During Pregnancy](#)) **(AIII)**.
- The Panel on Treatment of Pregnant Women with HIV Infection and Prevention of Perinatal Transmission emphasizes the **importance of counseling and informed decision-making** with regard to all ARV regimens for people living with HIV **(AIII)**. See [Appendix D: Dolutegravir Counseling Guide for Health Care Providers](#) for more information.

**Rating of Recommendations:** A = Strong; B = Moderate; C = Optional

**Rating of Evidence:** I = One or more randomized trials with clinical outcomes and/or validated laboratory endpoints; II = One or more well-designed, nonrandomized trials or observational cohort studies with long-term clinical outcomes; III = Expert opinion



## Pregnant Women Living with HIV Who Are Currently Receiving Antiretroviral Therapy (Last updated December 12, 2019; last reviewed December 12, 2019)

### Panel's Recommendations

- Women living with HIV who are receiving antiretroviral therapy (ART) and who present for pregnancy care should continue their ART during pregnancy, provided that the regimen is tolerated, safe, and effective in suppressing viral replication (defined as a regimen that maintains an HIV viral load less than lower limits of detection of the assay) **(AII)**.
- Women who present during pregnancy on drugs that are not recommended for use because of toxicity (e.g., stavudine, didanosine) should stop taking these drugs and be switched to other antiretroviral (ARV) drugs that are recommended for use in pregnancy **(AIII)**. See [Table 5](#) for more information.
- For pregnant women who are receiving dolutegravir (DTG) and present to care during pregnancy, providers should counsel these women about the risks and benefits of continuing DTG or switching to another ARV regimen **(AIII)**. In most cases, the Panel on Treatment of Pregnant Women with HIV Infection and Prevention of Perinatal Transmission recommends **continuation** of DTG **(AIII)**.
- There are no data on the use of two-drug regimens during pregnancy (e.g., DTG plus lamivudine, DTG plus rilpivirine); women who present to care on one of these regimens should switch regimens or add additional ARV agents to these regimens.
- Regimens that contain atazanavir/cobicistat, darunavir/cobicistat, or elvitegravir/cobicistat are associated with pharmacokinetic changes and an increased risk of virologic failure in the second and third trimesters of pregnancy (see [Table 4](#) and [Table 5](#)); when a pregnant woman presents to care on one of these regimens, providers should consider switching her to a more effective regimen that is recommended for use in pregnant women **(BIII)**. If one of these regimens is continued, absorption should be optimized, and viral load should be monitored frequently (i.e., every 1–2 months).
- If an ARV regimen is altered during pregnancy, drugs in the new regimen should include ARV drugs that are recommended for use in pregnancy (see [Table 4](#) and [Table 5](#)) **(BIII)**, and more frequent virologic monitoring is warranted **(CIII)**.
- ARV drug-resistance testing should be performed to assist the selection of active drugs when changing ARV regimens in pregnant women who are experiencing virologic failure on ART and who have HIV RNA levels >500 copies/mL to 1,000 copies/mL **(AII)**. In individuals who have HIV RNA levels >500 copies/mL but <1,000 copies/mL, testing may be unsuccessful but should still be considered **(BII)**. See [Lack of Viral Suppression](#) for more information.
- Clinicians should discuss future reproductive plans and timing as well as the risks and benefits of conceiving on specific ARV medications and use of appropriate contraceptive options to prevent unintended pregnancy **(AIII)**.

**Rating of Recommendations:** A = Strong; B = Moderate; C = Optional

**Rating of Evidence:** I = One or more randomized trials with clinical outcomes and/or validated laboratory endpoints; II = One or more well-designed, nonrandomized trials or observational cohort studies with long-term clinical outcomes; III = Expert opinion

# **Pregnant Women Living with HIV Who Have Previously Received Antiretroviral Medications but Are Not Currently Receiving Any Antiretroviral Medications** (Last updated December 24, 2019; last reviewed December 24, 2019)

## **Panel's Recommendations**

- Obtain an accurate history of all prior antiretroviral (ARV) medications used for HIV treatment or prevention of HIV transmission, including virologic efficacy, the patient's tolerance of the medications, the results of prior resistance testing, and problems with adherence (**AIII**).
- Choose and initiate an antiretroviral therapy (ART) regimen based on results of prior resistance testing, prior ARV drug use, concurrent medical conditions, and current recommendations for ART in pregnancy (see [Table 5](#)) (**AII**).
- If HIV RNA is above the threshold for resistance testing (i.e., >500 to 1,000 copies/mL), ARV drug-resistance testing should be performed prior to starting an ARV drug regimen (see [Antiretroviral Drug Resistance and Resistance Testing in Pregnancy](#)) (**AIII**).
- ART should be initiated prior to receiving results of current ARV resistance assays. ART should be modified based on the results of the resistance assay, if necessary (**BIII**).
- If the ART regimen results in insufficient viral suppression, repeat resistance testing and assess other considerations, including adherence, food requirements, and drug interactions (**AII**).
- Consider consulting an HIV treatment specialist when choosing an ART regimen for women who previously received ARV drugs or modifying ART in those who are not fully suppressed (**BIII**).

**Rating of Recommendations:** A = Strong; B = Moderate; C = Optional

**Rating of Evidence:** I = One or more randomized trials with clinical outcomes and/or validated laboratory endpoints; II = One or more well-designed, nonrandomized trials or observational cohort studies with long-term clinical outcomes; III = Expert opinion

## Monitoring of the Woman and Fetus During Pregnancy (Last updated December 24, 2019; last reviewed December 24, 2019)

### Panel's Recommendations

- Plasma HIV RNA levels of pregnant women with HIV should be monitored at the initial antenatal visit (**AI**), 2 to 4 weeks after initiating (or changing) an antiretroviral (ARV) drug regimen (**BI**), monthly until RNA levels are undetectable (**BIII**), and then at least every 3 months during pregnancy (**BIII**). HIV RNA levels also should be assessed at approximately 34 to 36 weeks' gestation to inform decisions about mode of delivery (see [Transmission and Mode of Delivery](#)) and to inform decisions about optimal management for the newborn (see [Antiretroviral Management of Newborns with Perinatal HIV Exposure or HIV Infection](#)) (**AIII**).
- CD4 T lymphocyte (CD4) cell count should be monitored at the initial antenatal visit (**AI**). Patients who have been on antiretroviral therapy (ART) for  $\geq 2$  years and who have had consistent viral suppression and CD4 counts that are consistently  $>300$  cells/mm<sup>3</sup> do not need to have their CD4 counts monitored after the initial antenatal visit during this pregnancy, per the Adult and Adolescent Antiretroviral Guidelines (**CIII**). Women who have been on ART for  $<2$  years, women with CD4 counts  $<300$  cells/mm<sup>3</sup>, and women with inconsistent adherence and/or detectable viral loads should have CD4 counts monitored every 3 to 6 months during pregnancy (**CIII**).
- HIV drug-resistance testing should be performed in women whose HIV RNA levels are above the threshold for standard resistance testing (i.e.,  $>500$  copies/mL to 1,000 copies/mL) before:
  - Initiating ART in ARV-naïve pregnant women who have not been previously tested for ARV resistance (**AII**);
  - Initiating ART in ARV-experienced pregnant women (**AIII**); or
  - Modifying ART regimens for women who become pregnant while receiving ARV drugs or women who have suboptimal virologic response to ARV drugs that were started during pregnancy (**AII**).
- ART should be initiated in pregnant women prior to receiving results of ARV-resistance tests. ART should be modified, if necessary, based on the results of the resistance assay (**BIII**).
- Laboratory testing for monitoring of complications of ARV drugs during pregnancy should be based on what is known about the adverse effects of the drugs a woman is receiving (**AIII**).
- Women who are taking ART during pregnancy should undergo standard glucose screening at 24 to 28 weeks' gestation (**AIII**). Some experts suggest glucose screening early in pregnancy for women who are receiving protease inhibitor (PI)-based regimens that were initiated before pregnancy, in accordance with recommendations for women who are at risk for glucose intolerance (**BIII**). For more information on PIs, see [Combination Antiretroviral Drug Regimens and Maternal and Neonatal Outcomes](#).
- Amniocentesis, if clinically indicated, should be performed on women with HIV only after initiation of an effective ART regimen and, ideally, when HIV RNA levels are undetectable (**BIII**). If a woman with detectable HIV RNA levels requires amniocentesis, consultation with an expert in the management of HIV in pregnancy should be considered (**BIII**).

**Rating of Recommendations:** A = Strong; B = Moderate; C = Optional

**Rating of Evidence:** I = One or more randomized trials with clinical outcomes and/or validated laboratory endpoints; II = One or more well-designed, nonrandomized trials or observational cohort studies with long-term clinical outcomes; III = Expert opinion

## Antiretroviral Drug Resistance and Resistance Testing in Pregnancy (Last updated December 24, 2019; last reviewed December 24, 2019)

### Panel's Recommendations

- HIV drug-resistance genotype testing should be performed in women living with HIV whose HIV RNA levels are above the threshold for resistance testing (i.e., >500 to 1,000 copies/mL) before:
  - Initiating antiretroviral therapy (ART) in antiretroviral (ARV)-naïve pregnant women who have not been previously tested for ARV resistance (AII),
  - Initiating ART in ARV-experienced pregnant women (AIII), or
  - Modifying ART regimens for women who are newly pregnant and receiving ART drugs or who have suboptimal virologic response to the ARV drugs started during pregnancy (AII).
- ART should be initiated in pregnant women prior to receiving results of ARV-resistance testing; ART should be modified, if necessary, based on the results of resistance assays (BIII).
- If the use of an integrase strand transfer inhibitor (INSTI) is being considered and INSTI resistance is a concern, providers should supplement standard resistance testing with a specific INSTI genotypic resistance assay (BIII). INSTI resistance may be a concern if:
  - A patient received prior treatment that included an INSTI, or
  - A patient has a history with a sexual partner on INSTI therapy.
- Documented zidovudine (ZDV) resistance does not affect the indications for use of intrapartum intravenous ZDV (see [Intrapartum Antiretroviral Therapy/Prophylaxis](#)) (BIII).
- Choice of ARV regimen for an infant born to a woman with known or suspected drug resistance should be determined in consultation with a pediatric HIV specialist, preferably before delivery (see [Antiretroviral Management of Newborns with Perinatal HIV Exposure or HIV Infection](#)) (AII).
- Pregnant women living with HIV should be given ART to maximally suppress viral replication, which is the most effective strategy for preventing development of resistance and minimizing risk of perinatal transmission (AII).
- All pregnant and postpartum women should be counseled about the importance of adherence to prescribed ARV medications to reduce the risk of developing resistance (AII).

**Rating of Recommendations:** A = Strong; B = Moderate; C = Optional

**Rating of Evidence:** I = One or more randomized trials with clinical outcomes and/or validated laboratory endpoints; II = One or more well-designed, nonrandomized trials or observational cohort studies with long-term clinical outcomes; III = Expert opinion

## Lack of Viral Suppression (Last updated December 24, 2019; last reviewed December 24, 2019)

### Panel's Recommendations

- Because maternal antenatal viral load correlates with the risk of perinatal transmission of HIV, suppression of HIV RNA to undetectable levels should be achieved as rapidly as possible (AII).
- For pregnant women who have not achieved viral suppression (after an adequate period of treatment):
  - Assess medication adherence, tolerability, dosing, potential problems with absorption, adherence to food requirements, and possible drug interactions.
  - If HIV RNA is >500 copies/mL, perform tests for resistance (AII).
  - Consult an HIV treatment expert and consider possible antiretroviral regimen modification (AIII).
- Intrapartum intravenous zidovudine prophylaxis and scheduled cesarean delivery at 38 weeks gestation are recommended for pregnant women living with HIV who have HIV RNA levels >1,000 copies/mL near the time of delivery (AII).

**Rating of Recommendations:** A = Strong; B = Moderate; C = Optional

**Rating of Evidence:** I = One or more randomized trials with clinical outcomes and/or validated laboratory endpoints; II = One or more well-designed, nonrandomized trials or observational cohort studies with long-term clinical outcomes; III = Expert opinion

## Stopping Antiretroviral Drugs during Pregnancy (Last updated December 24, 2019; last reviewed December 24, 2019)

### Panel's Recommendations

- If an antiretroviral (ARV) drug regimen must be stopped during pregnancy (e.g., for severe toxicity), all ARV drugs should be stopped simultaneously, and a complete, effective antiretroviral therapy regimen should be reinitiated as soon as possible (AIII).

**Rating of Recommendations:** A = Strong; B = Moderate; C = Optional

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## Special Populations: Hepatitis B Virus/HIV Coinfection (Last updated December 24, 2019; last reviewed December 24, 2019)

### Panel's Recommendations

- All pregnant women living with HIV should be screened during the current pregnancy for:
  - Hepatitis B virus (HBV) infection, unless they are already known to have HBV/HIV coinfection or have serologic documentation of HBV immunity, and
  - Hepatitis C virus (HCV) infection, unless they are already known to have HCV/HIV coinfection (see [Hepatitis C Virus/HIV Coinfection](#)) (AIII).
- All pregnant women with HIV who screen negative for HBV infection (i.e., HBV surface antigen negative, HBV core antibody negative, and HBV surface antibody negative) or who lack HBV immunity (i.e., HBV surface antibody negative) should receive the HBV vaccine series (AII).
- Women with chronic HBV infection who have not already received the hepatitis A virus (HAV) vaccine series should be screened for immunity to HAV. If they screen negative for HAV immunoglobulin G antibody, they should receive the HAV vaccine series (AIII).
- All pregnant and postpartum women with HBV/HIV coinfection should receive antiretroviral therapy (ART) that includes tenofovir disoproxil fumarate (TDF) plus lamivudine or emtricitabine (AI). If a woman with HBV/HIV coinfection becomes pregnant while virally suppressed on an antiretroviral regimen that includes tenofovir alafenamide (TAF), she can be offered the choice of continuing TAF or switching from TAF to TDF (BIII).
- Pregnant women with HBV/HIV coinfection who are receiving ART should be counseled about signs and symptoms of liver toxicity, and liver transaminases should be assessed 1 month after initiating ART and at least every 3 months thereafter during pregnancy (BIII).
- During and after pregnancy, women with chronic HBV should be counseled on the importance of continuing anti-HBV medications indefinitely. If ART that includes medications with anti-HBV activity is discontinued in women with HBV/HIV coinfection, frequent monitoring of liver function tests for potential exacerbation of HBV infection is recommended, with prompt re-initiation of treatment for HBV when a flare is suspected (BIII).
- Decisions concerning mode of delivery of the infant in a pregnant woman with HBV/HIV coinfection should be based on standard obstetric and HIV-related indications alone; HBV/HIV coinfection does not necessitate a cesarean delivery if not otherwise indicated (see [Transmission and Mode of Delivery](#)) (AIII).
- Within 12 hours of birth, infants born to women with HBV should receive hepatitis B immune globulin and the first dose of the HBV vaccine series (AI).

**Rating of Recommendations:** A = Strong; B = Moderate; C = Optional

**Rating of Evidence:** I = One or more randomized trials with clinical outcomes and/or validated laboratory endpoints; II = One or more well-designed, nonrandomized trials or observational cohort studies with long-term clinical outcomes; III = Expert opinion

## Special Populations: Hepatitis C Virus/HIV Coinfection (Last updated December 24, 2019; last reviewed December 24, 2019)

### Panel's Recommendations

- All pregnant women with HIV should be screened during the current pregnancy for hepatitis C virus (HCV) infection unless they are known to have HCV/HIV coinfection (**AIII**).
  - HCV screening should be repeated later in pregnancy in women who initially screen negative for HCV but who have persistent or new risk factors for HCV (e.g., new or ongoing injection or intranasal substance use) (**AIII**).
- All pregnant women with HIV should also be tested for hepatitis B virus (HBV) infection, unless they are known to have HBV/HIV coinfection or if they have serologic documentation of HBV immunity (see [Hepatitis B Virus/HIV Coinfection](#)).
- Women with HCV infection who have not already received the hepatitis A virus (HAV) vaccine series should be screened for immunity to HAV (**AIII**). If they screen negative for HAV antibodies (IgG or IgG plus IgM), they should receive the HAV vaccine series (**AIII**).
- All pregnant women with HIV and/or HCV who screen negative for HBV infection (i.e., HBV surface antigen negative, HBV core antibody negative, and HBV surface antibody negative) or who lack HBV immunity (i.e., HBV surface antibody negative) should receive the HBV vaccine series (**AII**).
- Currently, treatment of HCV during pregnancy **is not recommended** due to the lack of safety data on the use of HCV direct-acting antiviral medications in pregnant women. When considering initiating HCV treatment in a pregnant woman with HIV coinfection, consultation with an expert in HIV and HCV is strongly recommended (**AIII**).
- Recommendations for antiretroviral therapy (ART) during pregnancy are the same for all women living with HIV, whether they have HCV or not (**AIII**).
- Pregnant women with HCV/HIV coinfection who are receiving ART should be counseled about the signs and symptoms of liver toxicity, and hepatic transaminases should be assessed 1 month following initiation of ART and at least every 3 months thereafter during pregnancy (**BIII**).
- Decisions concerning the mode of infant delivery in pregnant women with HCV/HIV coinfection should be based on standard obstetric and HIV-related indications alone; HCV coinfection does not necessitate cesarean delivery when not otherwise indicated (see [Transmission and Mode of Delivery](#)) (**AIII**).
- Infants born to women with HCV/HIV coinfection should be evaluated for HCV infection (**AIII**). Decisions regarding the specific type of assays to use for HCV screening in children and the timing of those assays should be made after consultation with an expert in pediatric HCV infection (**AIII**).

**Rating of Recommendations:** A = Strong; B = Moderate; C = Optional

**Rating of Evidence:** I = One or more randomized trials with clinical outcomes and/or validated laboratory endpoints; II = One or more well-designed, nonrandomized trials or observational cohort studies with long-term clinical outcomes; III = Expert opinion



## HIV-2 Infection and Pregnancy (Last updated December 12, 2019; last reviewed December 12, 2019)

### Panel's Recommendations

- HIV-2 infection should be considered in pregnant women who are from—or who have partners who are from—countries in which the disease is endemic and who have positive results on an HIV-1/HIV-2 antibody or HIV-1/HIV-2 antigen/antibody immunoassay. They should be tested with a supplemental HIV-1/HIV-2 antibody differentiation assay. If they have only HIV-2 infection, the test will be negative for HIV-1 antibodies and positive for HIV-2 antibodies (**AII**).
- Pregnant women living with HIV-2 should be treated as per guidelines for HIV-1 mono-infection but using antiretroviral drugs that are active against HIV-2. Non-nucleoside reverse transcriptase inhibitors and enfuvirtide are not active against HIV-2 and **should not be used** (**AIII**).
- No randomized clinical trials have been performed to address when to start treatment or what the optimal treatment is for HIV-2 infection (**AIII**). A regimen with two nucleoside reverse transcriptase inhibitors and integrase strand transfer inhibitors or certain boosted protease inhibitors is recommended for all pregnant women with HIV-2 infection (**AIII**).
- Dolutegravir (irrespective of trimester), raltegravir, ritonavir-boosted darunavir, or ritonavir-boosted lopinavir plus a dual-nucleoside reverse transcriptase inhibitor (NRTI) backbone of abacavir plus lamivudine or tenofovir disoproxil fumarate plus emtricitabine or lamivudine are recommended for treating HIV-2 mono-infection in pregnant women and in women trying to conceive (**AIII**). Zidovudine (ZDV) plus lamivudine can be used as an alternative dual-NRTI backbone. See [Updated Guidance about the Use of Dolutegravir in Pregnancy in Recommendations for the Use of Antiretroviral Drugs in Pregnancy](#) and [Appendix D: Dolutegravir Counseling Guide for Health Care Providers](#).
- As with HIV-1, the possibility of hepatitis B virus/HIV-2 coinfection should be considered when choosing an antiretroviral regimen to treat HIV-2 (**AI**), see [Hepatitis B Virus/HIV Coinfection](#).
- All infants born to women with HIV-2 infection (who do not have HIV-1 infection) should receive the 4-week ZDV prophylactic regimen (**BIII**).
- In the United States, where safe infant formula is readily available, breastfeeding **is not recommended** for infants born to mothers with HIV-2 infection (**AIII**).

**Rating of Recommendations:** A = Strong; B = Moderate; C = Optional

**Rating of Evidence:** I = One or more randomized trials with clinical outcomes and/or validated laboratory endpoints; II = One or more well-designed, nonrandomized trials or observational cohort studies with long-term clinical outcomes; III = Expert opinion

## Prenatal Care, Antiretroviral Therapy, and HIV Management in Women with Perinatal HIV Infection (Last updated December 24, 2019; last reviewed December 24, 2019)

### Panel's Recommendations

- The management of prenatal care and general principles of antiretroviral therapy (ART) and HIV management do not differ between pregnant women with perinatally acquired HIV (PHIV) and those with nonperinatally acquired HIV (**AII**).
- Using the same guiding principles that are used for heavily ART-experienced adults, optimal ART regimens should be selected based on resistance testing, ART treatment history, and pill burden (**AII**).
- Consultation with experts in HIV and pregnancy is recommended when the presence of extensive drug resistance warrants the use of antiretroviral drugs for which there is limited experience in pregnancy (**AIII**).
- Pregnant women with PHIV warrant enhanced focus on adherence interventions during pregnancy and after delivery (**AII**).

**Rating of Recommendations:** A = Strong; B = Moderate; C = Optional

**Rating of Evidence:** I = One or more randomized trials with clinical outcomes and/or validated laboratory endpoints; II = One or more well-designed, nonrandomized trials or observational cohort studies with long-term clinical outcomes; III = Expert opinion

## Panel's Recommendations

- When acute HIV infection is suspected in pregnancy or during breastfeeding, a plasma HIV RNA test should be obtained in conjunction an antigen/antibody immunoassay test (see [Acute and Recent \[Early\] HIV Infection](#) in the [Adult and Adolescent Antiretroviral Guidelines](#) and the Centers for Disease Control and Prevention [HIV testing algorithm](#) for more information) (AII).
- Repeat HIV testing in the third trimester is recommended for pregnant women with initial negative HIV test results who are known to be at risk of acquiring HIV, who are receiving care in facilities that have an HIV incidence of  $\geq 1$  case per 1,000 pregnant women per year, those who reside in jurisdictions with elevated HIV incidence, or those who reside in states that require third-trimester testing (see [Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health Care Settings](#)) (AII).
- All pregnant women with acute or recent HIV infection should start antiretroviral therapy (ART) as soon as possible to prevent perinatal transmission, with the goal of rapidly suppressing plasma HIV RNA below detectable levels (AI).
- In women with acute HIV infection, baseline genotypic resistance testing should be performed simultaneously with initiation of ART (AII), and the regimen should be adjusted, if necessary, to optimize virologic response (BIII).
- Dolutegravir plus tenofovir disoproxil fumarate (TDF) plus emtricitabine (FTC) is the Preferred ART regimen for pregnant and breastfeeding women with acute HIV, irrespective of trimester (see [Table 4](#), [Table 5](#), and [Recommendations for Use of Antiretroviral Drugs During Pregnancy](#) and [Appendix D: Dolutegravir Counseling Guide for Health Care Providers](#)) (AII).
- Alternatively, raltegravir plus TDF plus FTC or a regimen that includes a ritonavir-boosted protease inhibitor can be initiated (AIII). See [Table 4](#), [Table 5](#), and Updated Guidance about the Use of Dolutegravir in Pregnancy in [Recommendations for Use of Antiretroviral Drugs During Pregnancy](#) for more information.
- The Panel on Treatment of Pregnant Women with HIV Infection and Prevention of Perinatal Transmission emphasizes the importance of counseling and informed decision-making regarding all antiretroviral (ARV) regimens for people living with HIV (AIII).
- Lactating women who receive a diagnosis of acute HIV infection should be counseled to discontinue breastfeeding.
- Infants born to women who received a diagnosis of acute HIV infection during pregnancy or breastfeeding are at high risk of perinatal HIV transmission and should receive an ARV regimen that is appropriate for this elevated risk (see [Table 6](#) in [Antiretroviral Management of Newborns with Perinatal HIV Exposure or HIV Infection](#)) (AII). Consulting a pediatric HIV specialist regarding appropriate infant management is strongly recommended (see [Antiretroviral Management of Newborns with Perinatal HIV Exposure or HIV Infection](#)).

**Rating of Recommendations:** A = Strong; B = Moderate; C = Optional

**Rating of Evidence:** I = One or more randomized trials with clinical outcomes and/or validated laboratory endpoints; II = One or more well-designed, nonrandomized trials or observational cohort studies with long-term clinical outcomes; III = Expert opinion



### Intrapartum Antiretroviral Therapy/Prophylaxis

#### Panel's Recommendations

- Women should continue taking their antepartum antiretroviral therapy (ART) on schedule as much as possible during labor and before scheduled cesarean delivery (AIII).
- Intravenous (IV) zidovudine (ZDV):
  - Should be administered to women with HIV if HIV RNA is known or suspected to be >1,000 copies/mL (or if HIV RNA is unknown) near delivery (AI).
    - Scheduled cesarean delivery at 38 weeks gestation (compared to 39 weeks for most indications) is recommended for women who have HIV RNA >1,000 copies/mL near delivery (see [Transmission and Mode of Delivery](#)) (AI).
  - Is not required for women who are receiving ART regimens and who have HIV RNA ≤50 copies/mL during late pregnancy and near delivery and no concerns regarding adherence to the ART regimen (BII).
  - May be considered for women with HIV RNA between 50 copies/mL and 999 copies/mL. There are inadequate data to determine whether administration of IV ZDV to women with HIV RNA levels between 50 copies/mL and 999 copies/mL provides any additional protection against perinatal HIV transmission. This decision can be made on a case-by-case basis, taking into consideration the woman's recent ART adherence and her preferences and involving expert consultation if needed (CII).
- Women who present in labor with unknown HIV status should undergo expedited antigen/antibody HIV testing (AII). See [Maternal HIV Testing and Identification of Perinatal HIV Exposure](#) for more information.
  - If the results are positive, an HIV-1/HIV-2 antibody differentiation test and an HIV-1 RNA assay should be done as soon as possible, and maternal IV ZDV and infant combination antiretroviral (ARV) prophylaxis should be initiated pending results of the differentiation test (AII).
  - If the maternal HIV differentiation test is positive or if acute infection is suspected because the differentiation test is negative but the HIV RNA test is positive, infant ARV drugs should be managed as discussed in [Antiretroviral Management of Newborns with Perinatal HIV Exposure or HIV Infection](#) (AI). Women with positive expedited test results should not initiate breastfeeding until HIV infection is definitively ruled out (see [Postpartum Follow-Up of Women Living with HIV Infection](#)) (AII).
  - If the maternal HIV differentiation test is negative and [acute HIV infection](#) has been reasonably excluded with a negative HIV RNA test result, the maternal and infant ARV drugs should be stopped (AIII).

**Rating of Recommendations:** A = Strong; B = Moderate; C = Optional

**Rating of Evidence:** I = One or more randomized trials with clinical outcomes and/or validated laboratory endpoints; II = One or more well-designed, nonrandomized trials or observational cohort studies with long-term clinical outcomes; III = Expert opinion

## Transmission and Mode of Delivery (Last updated December 24, 2019; last reviewed December 24, 2019)

### Panel's Recommendations

- Scheduled cesarean delivery at 38 weeks gestation to minimize perinatal transmission of HIV is recommended for women with HIV RNA levels >1,000 copies/mL or unknown HIV levels near the time of delivery, irrespective of administration of antepartum antiretroviral therapy (ART) (AII).
- Scheduled cesarean delivery performed solely for prevention of perinatal transmission in women receiving ART with HIV RNA ≤1,000 copies/mL **is not routinely recommended** given the low rate of perinatal transmission in this group (AII).
- In women with HIV RNA levels ≤1,000 copies/mL, if scheduled cesarean delivery or induction is indicated, it should be performed at the standard time for obstetrical indications (AII).
- In women with an HIV RNA >1,000 copies/mL or unknown HIV RNA level who present in spontaneous labor or with ruptured membranes, there is insufficient evidence to determine whether cesarean delivery reduces the risk of perinatal HIV transmission. Management of women originally scheduled for cesarean delivery because of HIV who present in labor must be individualized at the time of presentation (BII). In these circumstances, consultation with an expert in perinatal HIV (e.g., telephone consultation with the National Perinatal HIV/AIDS Clinical Consultation Center at 1-888-448-8765) may be helpful in rapidly developing an individualized delivery plan.
- In women on ART with HIV RNA ≤1,000 copies/mL, duration of ruptured membranes is not associated with an increased risk of perinatal transmission and **is not an indication for cesarean delivery to prevent HIV transmission** (BII).

**Rating of Recommendations:** A = Strong; B = Moderate; C = Optional

**Rating of Evidence:** I = One or more randomized trials with clinical outcomes and/or validated laboratory endpoints; II = One or more well-designed, nonrandomized trials or observational cohort studies with long-term clinical outcomes; III = Expert opinion

## Other Intrapartum Management Considerations (Last updated December 24, 2019; last reviewed December 24, 2019)

### Panel's Recommendations

- Artificial rupture of membranes (ROM) can be performed for standard obstetric indications in virologically suppressed women with HIV who are on antiretroviral therapy (ART) (BII).
- The following procedures should generally be avoided because of a potential increased risk of perinatal HIV transmission, unless there are clear obstetric indications:
  - Artificial ROM (BIII) **in women who have detectable viral load**;
  - Routine use of fetal scalp electrodes for fetal monitoring (BIII); and
  - Operative delivery with forceps or a vacuum extractor (BIII).
- The ART regimen a woman is receiving should be taken into consideration when treating excessive postpartum bleeding caused by uterine atony.
  - In women who are receiving a cytochrome P450 (CYP) 3A4 enzyme inhibitor (e.g., a protease inhibitor, integrase inhibitor, cobicistat), methergine should be used only if no alternative treatments for postpartum hemorrhage are available and the need for pharmacologic treatment outweighs the risks. If methergine is used, it should be administered at the lowest effective dose for the shortest possible duration (BIII).
  - In women who are receiving a CYP3A4 enzyme inducer such as nevirapine, efavirenz, or etravirine, additional uterotonic agents may be needed because of the potential for decreased methergine levels and inadequate treatment effect (BII).

**Rating of Recommendations:** A = Strong; B = Moderate; C = Optional

**Rating of Evidence:** I = One or more randomized trials with clinical outcomes and/or validated laboratory endpoints; II = One or more well-designed, nonrandomized trials or observational cohort studies with long-term clinical outcomes; III = Expert opinion

## Postpartum Follow-Up of Women Living with HIV (Last updated December 24, 2019; last reviewed December 24, 2019)

### Panel's Recommendations

- Antiretroviral therapy (ART) is currently recommended for all individuals living with HIV to reduce the risk of disease progression and to prevent the sexual transmission of HIV (AI).
- ART should be continued after delivery (AI). Any plans for modifying ART after delivery should be made in consultation with the woman and her HIV care provider, ideally before delivery, taking into consideration the recommended regimens for nonpregnant adults (AIII) and plans for future pregnancies.
- Clinicians should discuss future reproductive plans and timing, as well as the risks and benefits of conceiving on specific antiretroviral (ARV) medications, and the use of appropriate contraceptive options to prevent unintended pregnancy (AIII).
- Because the immediate postpartum period poses unique challenges to ARV adherence, arrangements for new or continued supportive services should be made before hospital discharge (AII).
- Contraceptive counseling should start during the prenatal period; a contraceptive plan should be developed prior to hospital discharge (AIII).
- Women with a positive rapid HIV antibody test during labor require immediate linkage to HIV care and comprehensive follow-up, including for confirmation of HIV infection (AII).
- Prior to hospital discharge, the woman should be given ARV medications for herself and her newborn to take at home (AIII).
- Breastfeeding **is not recommended** for women in the United States who have confirmed HIV or are presumed to be living with HIV because safer infant feeding alternatives are available (AI).
- Infant feeding counseling, including a discussion of potential barriers to formula feeding, should begin during the prenatal period, and this information should be reviewed after delivery (AIII).

**Rating of Recommendations:** A = Strong; B = Moderate; C = Optional

**Rating of Evidence:** I = One or more randomized trials with clinical outcomes and/or validated laboratory endpoints; II = One or more well-designed, nonrandomized trials or observational cohort studies with long-term clinical outcomes; III = Expert opinion

## Counseling and Managing Women Living with HIV in the United States Who Desire to Breastfeed (Last updated December 24, 2019; last reviewed December 24, 2019)

### Panel's Recommendations

- In the United States, the safest way to feed infants born to women with HIV is with formula, because breastfeeding presents an ongoing risk of HIV exposure after birth, and because suppressive maternal antiretroviral therapy significantly reduces, but does not eliminate, the risk of transmitting HIV through breastfeeding. Therefore, breastfeeding **is not recommended** for women living with HIV in the United States (AII).
- Women who have questions about breastfeeding or who desire to breastfeed should receive patient-centered, evidence-based counseling on infant feeding options (AIII).
- When women with HIV choose to breastfeed, they should be counseled to use harm-reduction measures to minimize the risk of HIV transmission to their infants (BIII).

**Rating of Recommendations:** A = Strong; B = Moderate; C = Optional

**Rating of Evidence:** I = One or more randomized trials with clinical outcomes and/or validated laboratory endpoints; II = One or more well-designed, nonrandomized trials or observational cohort studies with long-term clinical outcomes; III = Expert opinion

# Antiretroviral Management of Newborns with Perinatal HIV Exposure or HIV Infection (Last Updated April 14, 2020; last reviewed April 14, 2020)

## Panel's Recommendations

- All newborns who were perinatally exposed to HIV should receive postpartum antiretroviral (ARV) drugs to reduce the risk of perinatal transmission of HIV (AI).
- Newborn ARV regimens administered at doses that are appropriate for the infant's gestational age should be initiated as close to the time of birth as possible, preferably within 6 to 12 hours of delivery (AII).
- A newborn's ARV regimen should be determined based on maternal and infant factors that influence the risk of perinatal transmission of HIV (AII). The uses of ARV regimens in newborns include:
  - **ARV Prophylaxis:** The administration of one or more ARV drugs to a newborn without documented HIV infection to reduce the risk of perinatal acquisition of HIV.
  - **Presumptive HIV Therapy:** The administration of a three-drug ARV regimen to newborns who are at highest risk of perinatal acquisition of HIV. Presumptive HIV therapy is intended to be preliminary treatment for a newborn who is later documented to have HIV, but it also serves as prophylaxis against HIV acquisition for those newborns who are exposed to HIV *in utero*, during the birthing process, or during breastfeeding and who do not acquire HIV.
  - **HIV Therapy:** The administration of a three-drug ARV regimen at treatment doses (called antiretroviral therapy [ART]) to newborns with documented HIV infection (see [Diagnosis of HIV Infection in Infants and Children](#)).
- A 4-week zidovudine (ZDV) ARV prophylaxis regimen can be used in newborns whose mothers received ART during pregnancy and had sustained viral suppression near delivery (defined as a confirmed HIV RNA level <50 copies/mL) and for whom there are no concerns related to maternal adherence (BII).
- Newborns at higher risk of perinatal acquisition of HIV should initiate presumptive HIV therapy (see Table 7 for recommended regimens). Newborns at higher risk of HIV acquisition include those born to women with HIV who:
  - Have not received antepartum or intrapartum ARV drugs (AI), or
  - Have received only intrapartum ARV drugs (AI), or
  - Have received antepartum ARV drugs but who did not achieve viral suppression near delivery (AII), or
  - Have primary or acute HIV infection during pregnancy (AII), or
  - Have primary or acute HIV infection while breastfeeding (AII).
- Newborns of women with unknown HIV statuses who test HIV positive on expedited testing during labor or shortly after birth should initiate an ARV regimen (either presumptive HIV therapy or two-drug ARV prophylaxis, based on clinician assessment of risk) (AII). If supplemental testing is negative, the ARV regimen should be discontinued (AII).
- For newborns with HIV infection, ART should be initiated (AI).
- The use of ARV drugs other than ZDV, lamivudine, and nevirapine cannot be recommended for any indication in premature newborns (<37 weeks gestational age) because of lack of dosing and safety data (BII).
- Providers with questions about ARV management of perinatal HIV exposure should consult the National Perinatal HIV Hotline (1-888-448-8765), which provides free clinical consultation on all aspects of perinatal HIV, including newborn care (AIII).

**Rating of Recommendations:** A = Strong; B = Moderate; C = Optional

**Rating of Evidence:** I = One or more randomized trials with clinical outcomes and/or validated laboratory endpoints; II = One or more well-designed, nonrandomized trials or observational cohort studies with long-term clinical outcomes; III = Expert opinion

## Diagnosis of HIV Infection in Infants and Children (Last updated December 24, 2019; last reviewed December 24, 2019)

### Panel's Recommendations

- Virologic assays (i.e., HIV RNA or HIV DNA nucleic acid tests [NATs]) that directly detect HIV must be used to diagnose HIV in infants and children aged <18 months with perinatal and postnatal HIV exposure; HIV antibody tests should not be used (AII).
- HIV RNA or HIV DNA NATs are generally equally recommended (AII).
- An assay that detects HIV non-B subtype viruses or Group O infections (e.g., an HIV RNA NAT or a dual-target total DNA/RNA test) is recommended for use in infants and children who were born to mothers with known or suspected non-B subtype virus or Group O infections (AII). If a mother of an infant acquired HIV outside of the United States and has had repeated undetectable HIV RNA by standard testing, consultation with a clinical virologist on more sensitive HIV nucleic acid testing may be indicated.
- Virologic diagnostic testing (see Figure 1 and 2) is recommended for all infants with perinatal HIV exposure at the following ages:
  - 14 to 21 days (AII)
  - 1 to 2 months (AII)
  - 4 to 6 months (AII)
- For infants who are at higher risk of perinatal HIV transmission, additional virologic diagnostic testing is recommended at birth (AII) and at 6 weeks after cessation of antiretroviral prophylaxis (BII).
- A positive virologic test should be confirmed as soon as possible by repeat virologic testing (AII).
- Definitive exclusion of HIV infection in nonbreastfed infants is based on two or more negative virologic tests, with one obtained at age  $\geq 1$  month and one at age  $\geq 4$  months, or two negative HIV antibody tests from separate specimens that were obtained at age  $\geq 6$  months (AII).
- Some experts confirm the absence of HIV at age 12 to 18 months in children with prior negative virologic tests by performing an HIV antibody test to document loss of maternal HIV antibodies (BIII).
- Since children aged 18 to 24 months with perinatal HIV exposure occasionally have residual maternal HIV antibodies, definitive exclusion or confirmation of HIV infection in children in this age group who remain HIV antibody-positive should be based on an HIV NAT and antibody retesting at 24 months (AII).
- Diagnostic testing in children with nonperinatal exposure only or in children with perinatal exposure aged >24 months relies primarily on the use of HIV antibody (or antigen/antibody) tests.
- When acute HIV infection is suspected, additional testing with an HIV NAT may be necessary to diagnose HIV infection (AII).

**Note:** The [National Clinician Consultation Center](#) provides consultations on issues related to the management of perinatal HIV infection (1-888-448-8765; 24 hours a day, 7 days a week).

**Rating of Recommendations:** A = Strong; B = Moderate; C = Optional

**Rating of Evidence:** I = One or more randomized trials in children<sup>†</sup> with clinical outcomes and/or validated endpoints; I\* = One or more randomized trials in adults with clinical outcomes and/or validated laboratory endpoints with accompanying data in children<sup>†</sup> from one or more well-designed, nonrandomized trials or observational cohort studies with long-term clinical outcomes; II = One or more well-designed, nonrandomized trials or observational cohort studies in children<sup>†</sup> with long-term outcomes; II\* = One or more well-designed, nonrandomized trials or observational studies in adults with long-term clinical outcomes with accompanying data in children<sup>†</sup> from one or more similar nonrandomized trials or cohort studies with clinical outcome data; III = Expert opinion

<sup>†</sup> Studies that include children or children and adolescents, but not studies limited to post-pubertal adolescents

## Initial Postnatal Management of the Neonate Exposed to HIV (Last updated December 24, 2019; last reviewed December 24, 2019)

### Panel's Recommendations

- All newborns who were perinatally exposed to HIV should receive appropriate antiretroviral (ARV) drugs as soon as possible after delivery (see [Antiretroviral Management of Newborns with Perinatal HIV Exposure or HIV Infection](#)) (AI).
- A complete blood count and differential should be performed on newborns as a baseline evaluation (BIII).
- Infants who are found to have hematologic abnormalities may need to discontinue ARV drugs. Clinicians should base the decision to discontinue ARV drugs on the individual needs of the patient. Consultation with an expert in pediatric HIV infection is advised if early discontinuation of ARV drugs is considered (CIII).
- When determining the timing for subsequent monitoring of hematologic parameters in infants, clinicians need to consider the infant's baseline hematologic values, gestational age at birth, and clinical condition; whether the infant is receiving zidovudine (ZDV), other ARV drugs, or certain concomitant medications; and the specific ARV drugs used in the mother's antepartum drug regimen (CIII).
- Hemoglobin and neutrophil counts should be remeasured 4 weeks after initiating an ARV regimen that contains ZDV and lamivudine (AI).
- Virologic tests are required to diagnose HIV infection in infants aged <18 months (see [Diagnosis of HIV Infection in Infants and Children](#)) (AII).
- To prevent *Pneumocystis jirovecii* pneumonia (PCP), all infants born to women with HIV should begin PCP prophylaxis at ages 4 to 6 weeks, after completing their ARV prophylaxis or an empiric HIV therapy regimen, unless there is adequate test information to presumptively exclude HIV infection (see the [Pediatric Opportunistic Infection Guidelines](#)) (AII).
- Health care providers should routinely inquire about infant feeding plans and/or breastfeeding desires, as well as the use of premasticated (prechewed or prewarmed) food. Counseling against premastication and discussion of safe infant feeding options should be provided (see [Counseling and Managing Women Living with HIV in the United States Who Desire to Breastfeed](#)) (AIII).

**Rating of Recommendations:** A = Strong; B = Moderate; C = Optional

**Rating of Evidence:** I = One or more randomized trials with clinical outcomes and/or validated laboratory endpoints; II = One or more well-designed, nonrandomized trials or observational cohort studies with long-term clinical outcomes; III = Expert opinion

## Long-Term Follow-Up of Infants Exposed to Antiretroviral Drugs (Last updated January 17, 2020; last reviewed January 17, 2020)

### Panel's Recommendation

- Children with *in utero* or neonatal exposure to antiretroviral (ARV) drugs who develop significant organ system abnormalities of unknown etiology, particularly of the nervous system or heart, should be evaluated for potential mitochondrial dysfunction (CIII).
- It is important that the long-term medical record of a child without HIV includes information about *in utero* and neonatal ARV exposure (BIII).

**Rating of Recommendations:** A = Strong; B = Moderate; C = Optional

**Rating of Evidence:** I = One or more randomized trials with clinical outcomes and/or validated laboratory endpoints; II = One or more well-designed, nonrandomized trials or observational cohort studies with long-term clinical outcomes; III = Expert opinion